SURGICAL KIT

S.I.N. Osteotome Kit – KOST

The S.I.N. Osteostome Kit - KOST is intended for specialized procedures, which must be performed by qualified professionals. The use of the product and surgical techniques are inherent to the professional's training. The use of the product must be performed in a surgical environment and in proper conditions for the health and safety of the patient.

PRODUCT DESCRITION

The S.I.N. Osteostome Kit - KOST is a Kit consisting of four Summers Osteotomes with Stop.

INDICATIONS OF USE

Osteotomes are used as surgical instruments during the procedures of bone compaction or partial lifting of the maxillary sinus, not being implantable. They allow the installation of bone-integrated implants, with no or little use of drills to betteruse of the remaining bone tissue of the patient, often avoiding the need for bone grafting.

OPERATION PRINCIPLE

The operation principle applicable to osteotomes is that of Lever, that is, purely mechanical. The force exerted at the distal (wider) end is transferred throughout the body of the instrument, to the proximal end, which acts at the surgical site by compacting the bone in a vertical and/or horizontal direction.

HOW TO USE

The Dental Surgeon should use the Osteotome in procedures of bone compaction or partial elevation of the maxillary sinus, following the aseptic and appropriate surgical techniques to each case. In the items described below, there is a suggested route for the use of Osteotomes, in cases of bone compaction and partial elevation of the maxillary sinus. After using the Osteotome, separate them from other materials, wash and sterilize them following the instructions in the Cleaning, Disinfection and Conditioning section described in this instruction manual.

Bone Compaction:

1. First of all, the bone is subjected to an initial perforation in the implant site to be fitted with the milling cutter shaft, and then followed with the helicoidal cutter to the planned depth;
2. Before using the instruments, it is recommended to mount the depth stop, in order not to exceed the pre-determined working depth.
3. Straight instruments allow easier access in the back area;
4. The larger diameter instruments are manually introduced, with slightly rotating movements or with slight hammer strokes, according to the length and diameter of the desired implant.
5. Careful insertion of the implant is recommended.

Partial lifting of the maxillary sinus floorboard:

1. First of all, the bone is subjected to a perforation in the implant site to be fitted with the milling cutter shaft, then the helicoidal cutter to the maxillary sinus floorboard boundary, with due care not to break such cortical with the cutter. This process assumes an exact planning in the radiological image;
2. Before using the instruments, it is recommended to mount the depth Stop in order not to exceed the pre-determined working depth. Depth stops are manually mounted on the instruments. Straight instruments allow easier access in the back area;
3. Upon completion of the cutting, the maxillary sinus floor is fractured using the osteotome of diameter of 2 mm, which requires an accurate radiological planning. It is recommended to work with depth stop, in order not to exceed the one previously defined in the planning. The instrument is advanced with slight hammer strokes, according to the desired length of the implant;

4. During lifting, prior to its installation, a filling material (autogenous bone or bone substitute) is applied to the implant bed. The material introduced has the effect of a cushion that raises the maxillary sinus membraneaccording to the hydraulic principle;
5. Careful insertion of the implant is recommended.
6. Depending on the availability and location in bone density, it may be necessary to alternate the use of osteotomes and cutters with progressive diameters to achieve satisfactory clinical results.

ATTENTION

The S.I.N. Osteotome Kit - KOST is intended for specialized procedures, which must be performed by qualified professionals in dentistry. The product must be used in a surgical environment and under adequate conditions for the health and safety of the patient.

PRECAUTIONS

The excessive use of the osteotomes, the bad positioning, added to the lever effort caused during the use can compromise the active tip of the osteotomes. The professional must be aware of the force exerted during the use of the product in order not to cause damage to the patient and to the product. The professional must: prepare an environment with sterile surgical dressing and field, submit the patient to a good buccal asepsis, avoid that during the application the product has contact with any non-sterile object in order to reduce to a minimum the risk of contamination. The professional must inform the patient of the adequate form of hygiene, the need for periodic monitoring, and the avoidance of physical effort after the surgery.

RECOMMENDATIONS

In order to use the S.I.N. Osteotome Kit - KOST, it is recommended that the professional must have taken a specialization course in Implant Dentistry or Oral and Maxillofacial Surgery. The professional must submit the instruments to a thorough visual inspection to diagnose cases mentioned above in the warnings.

CONTRAINDICATIONS

The S.I.N. Osteotome Kit - KOST has no contraindications as long as its recommendations are correctly followed and it is used by a specialized professional, who will be responsible for the proper planning of the surgical procedure in which the S.I.N. Osteotome Kit will be used.

SIDE EFFECTS

The S.I.N. Osteostome Kit - KOST is used to assist in the installation of prosthetic components on dental implants, thus adverse effects shall occur only if the choice or use of the instrument is not appropriate.

WARNING

Do not use the instruments if you notice cracks, wear or oxidation/corrosion spots. This may cause problems in the functioning of the products and installation of prosthetic components. All the items may present natural wear and tear generated by use and must be replaced whenever possible.

TRACEABILITY

All S.I.N. - Implant System products have sequential batches that allow for traceability, thus providing greater security to the professional who is qualified for the procedure. Through this lot number it is possible to know the entire history of the product from the manufacturing process to the moment of distribution.

STORAGE

The Osteotome S.I.N. Kit - KOST should be stored in a cool, dry place, at a maximum temperature of 35°C and protected from direct sunlight.

HANDLING

Once sterilized, the instruments should be handled only in a sterile environment by properly dressed professionals in appropriate attire at the time of implant installation surgery.

DISPOSAL OF MATERIAL

The disposal of materials must be done according to hospital standards and local legislation in force.

TRANSPORTATION

The S.I.N. Osteotome Kit - KOST should be transported in a proper way to avoid falls and stored at a maximum temperature of 35°C, protected from heat and humidity. It must be transported in its original packaging.

COMPLEMENTARY INFORMATIONS

Multiple use product. Exclusive for Odontological use. Passible of Reprocessing. See cleaning and sterilization conditions contained in this use instruction. In case of any incident caused by the product, the professional must inform the manufacturer immediately. If you need the printed version of this instruction for use, without any cost, please request by e-mail to sin@sinimplante.com.br or call to 0800 770 8290 will receive until 7 days calendar.

CLEANING INSTRUCTIONS

1. Remove manually all surgical instruments from the kit. Remove the kit box parts (lid, tray and bottom).
2. Prepare the enzymatic detergent, according to manufacturer's recommendation.
3. Immerse the trays into the prepared detergent solution and keep in contact for at least 5 minutes, then using a soft bristle brush, scrub the parts to remove organic matter from the products.
4. Remove trays from detergent solution and rinse with tap water for 1 minute, repeat the rinse for two more times, a total of three rinses of 1 minute each.
5. Visual inspection of each part for cleaning process residue or organic waste from product use.
6. If residue is detected in the product, repeat the cleaning process until the residue is completely removed.
7. Dry with a soft, clean, dry cloth or disposable paper.

RECOMMENDATIONS

a. Use the proper PPEs (gloves, masks, goggles, caps, etc.).
b. Start the cleaning right after the surgical use.
c. Never let the instruments dry with organic waste after the surgical use.
d. Never let the instrument dry naturally after cleaning.
e. Never use saline solutions, include sodium hypochlorite, disinfectant, hydrogen peroxide or alcohol to cleaning or rinsing the surgical instruments and kits.
f. Never use steel wool and abrasive products, so that the instruments are not damaged.
g. Do not stack the instruments in lots to avoid the deformation of smaller and delicate pieces.

STERILIZATION

Reusable product and provided non-sterile. It must be clean and sterilized in autoclave before use.

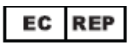
1. Dry all instruments before the steam sterilization cycle.
2. The product must be enclosed in a steam sterilizable wrap.
3. Steam sterilize in cycles of 121°C at 1 ATM pressure for 30 minutes or of 134°C at 2 ATM pressure for 20 minutes. Drying time 30 minutes.
4. Always accommodate the case in autoclave over a plane surface and away of device walls.
5. Never stack objects or other cases.

RECOMMENDATIONS

a. Sterilize the products in the same day or one day earlier the procedure.
b. The chemical sterilization is not recommended, once some products may cause the discoloration and damages to the case.
c. Do not use temperature higher than 60°C to drying process.
d. Do not use dry heat stoves for sterilization of the instruments and kits from S.I.N. - Implant System.

LIFE TIME

The S.I.N. Osteotome Kit - KOST can be reprocessed, depending on proper handling, cleaning and sterilization, up to 250 times.

	NÃO ESTÉRIL	NON-ESTERILE	NO ESTÉRIL
	CONSULTAR AS INSTRUÇÕES DE USO	CONSULT INSTRUCTIONS FOR USE	CONSULTE LAS INSTRUCCIONES DE USO
	MARCAÇÃO CE	CE MARK	MARCA CE
	MANTENHA SECO	KEEP DRY	MANTÉNGALO SECO
	MANTENHA AO ABRIGO DO SOL	KEEP AWAY FROM SUNLIGHT	MANTÉNGALO LEJOS DE LA LUZ SOLAR
	NÃO UTILIZAR SE A EMBALAGEM ESTIVER VIOLADA	DO NOT USE IF PACKAGE IS DAMAGED	NO LO UTILICE SI EL ENVOLTORIO ESTÁ DAÑADO
	ATENÇÃO	CAUTION	PRECAUCIÓN
	REPRESENTANTE AUTORIZADO NA COMUNIDADE EUROPEIA	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REPRESENTANTE AUTORIZADO EN LA COMUNIDAD EUROPEA
	LIMITE SUPERIOR DE TEMPERATURA	UPPER LIMIT OF TEMPERATURE	LÍMITE SUPERIOR DE TEMPERATURA
Rx only	ATENÇÃO: A LEI FEDERAL (EUA) LIMITA A VENDA DESTE DISPOSITIVO POR OU POR ORDEM DE UM PROFISSIONAL DE SAÚDE LICENCIADO.	CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PRACTITIONER.	PRECAUCIÓN: LAS LEYES FEDERALES (USA) RESTRINGEN LA VENTA DE ESTE DISPOSITIVO POR O EN EL ORDEN DE UN PROFESIONAL DE LA SALUD LICENCIADO.
	FABRICANTE	MANUFACTURE	FABRICANTE
	DATA DE FABRICAÇÃO	DATE OF MANUFACTURE	FECHA DE FABRICACIÓN
	CÓDIGO DE REFERÊNCIA	REFERENCE CODE	CÓDIGO DE REFERENCIA
	DISPOSITIVO MÉDICO	MEDICAL DEVICE	DISPOSITIVO MEDICO
	IDENTIFICADOR ÚNICO DO DISPOSITIVO	UNIQUE DEVICE IDENTIFIER	IDENTIFICADOR DE DISPOSITIVO ÚNICO
	IMPORTADOR	IMPORTER	IMPORTADOR
	DISTRIBUIDOR	DISTRIBUTOR	DISTRIBUIDOR
	PAÍS DE FABRICAÇÃO	COUNTRY OF MANUFACTURE	PAÍS DE FABRICACIÓN
	LOTE	BATCH CODE	LOTE
	EMBALAGEM RECICLÁVEL	RECYCLABLE PACKAGING	EMBALAJE RECICLABLE

DEVELOPED AND MANUFACTURED BY:
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